PEARSON, J.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

JANE OLSZESKI, Plaintiff, v. ETHICON WOMEN'S HEALTH AND UROLOGY, *et al.*, Defendants.	)	CASE NO. 5:19CV1787 JUDGE BENITA Y. PEARSON **MEMORANDUM OF OPINION AND ORDER (*CASE-SPECIFIC*)** [Resolving ECF Nos. 130, 132, 133, 134, 135, 137, 140, and 188]

Pending are Plaintiff's and Defendants Ethicon, Inc. and Johnson & Johnson's motions to strike report and/or exclude testimony of an expert witness (case-specific) (ECF Nos. 130, 132, 133, 134, 135, 137, 140, and 188). The Court held a *Daubert* Hearing via Zoomgov.com on February 11, 2022. The Court has been advised, having reviewed the record, the parties' briefs, and the applicable law.

I. Background

U.S. District Judge Joseph R. Goodwin presided over *In re: Boston Scientific Corp. Pelvic Repair System Products Liability Litig.*, MDL No. 2327 in S.D. W.Va. Plaintiff's implanting physician is Melissa S. Vassas, D.O. On Feb. 24, 2009, Plaintiff underwent a procedure that included IUD removal, hysteroscopy, and the implantation of two mesh devices, the Ethicon TVT-O polypropylene sling and the Boston Scientific Corp. Pinnacle polypropylene device, in her lower pelvis. Ethicon's Gynecare TVT-Obturator pelvic mesh product treated Plaintiff's stress urinary incontinence ("SUI"), and was installed through her left obturator

muscle. Boston Scientific's Pinnacle Pelvic Floor Repair Kit treated Plaintiff's pelvic prolapse, and was installed through her sacrospinous ligament. Plaintiff filed a Complaint in 2013. In the Amended Complaint (ECF No. 56), Plaintiff is pursuing both defective design and failure to warn claims under Ohio law regarding these polypropylene pelvic mesh products.[1] Plaintiff also maintains a non-conformance with representation claim against Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon" or "Defendants"). Whether Plaintiff's claimed injuries were caused by her Gynecare TVT-Obturator (the "TVT-O") (a sling manufactured by Ethicon) or her Pinnacle Pelvic Floor Repair Kit (the "Pinnacle") (manufactured by Boston Scientific) is a primary issue in this case. Plaintiff's "primary disabling conditions are right and left pudendal neuralgia and right and left obturator neuralgia," that her "[r]ight and left pudendal neuralgia . . . is the primary cause of her dyspareunia," "bladder symptoms," "pelvic pain" and "lack of clitoral sensation," and that her mesh implants are also responsible for "Erosion, pelvic floor dysfunction, [and] levator spasm." ECF No. 132-2 at PageID #: 13692-98.

Pelvic organ prolapse is when one or more of the organs in the pelvis slip down from their normal position and bulge into the vagina. Pudendal neuralgia is long-term pelvic pain that originates from damage or irritation of the pudendal nerve. Obturator neuralgia is an uncommon cause of medial thigh pain that does not extend below the knee and occurs most often after trauma.

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[1] Plaintiff settled her claims against Boston Scientific Corp. On Nov. 19, 2021, the Court entered an Order (ECF No. 125) dismissing all claims against Boston Scientific Corp. with prejudice.

Plaintiff had mesh removal surgeries on October 21, 2019, July 9, 2020, and July 13, 2021. The July 2021 surgery at the Cleveland Clinic removed mesh from "the left sacrospinous ligament and left obturator muscle." Urology Operative Report (ECF No. 157-3) at PageID #: 20221. The operative report from that procedure documents how, when the surgeon located mesh at the sacrospinous ligament (where the Pinnacle mesh was installed) and cut it, "a small piece of the [mesh] arm retracted deep into the pelvis," where the surgeon was unable to locate and remove it. ECF No. 157-3 at PageID #: 20223. The surgeon then attempted to remove mesh from the obturator internus muscle (where the TVT-O mesh was installed), and reported that" [g]rasping the mesh with allis clamps we were able to remove the area of mesh identified." ECF No. 157-3 at PageID #: 20223. Although the report notes at this point that "[b]oth pieces of mesh were sent to pathology," ECF No. 157-3 at PageID #: 20223, the Surgical Pathology Report (ECF No. 157-4) for the procedure described only a single sample. Cleveland Clinic was able to produce only a single pathology sample after the surgery concluded. *See* Declaration of Rachel Wright, Esq. (ECF No. 157-5) at PageID #: 20229, ¶ 5.

Howard B. Goldman, M.D. performed the July 2021 surgery. Dr. Goldman confirmed that he removed two pieces of mesh and stated that the pathology report likely referred to one sample because the two pieces he removed were "clumped together."

Plaintiff's design defect claim (Count II; Ohio Rev. Code § 2307.75), failure to warn claim (Count III; Ohio Rev. Code § 2307.76), and nonconformance with representation claim (Count IV; Ohio Rev. Code § 2307.77) in the Amended Complaint (ECF No. 56) remain pending.

II. ECF Nos. 140 and 188 - Margaret Mueller, M.D., FACCS, FACOG

A.

Plaintiff challenges Dr. Mueller's opinions related to the position and the placement of the TVT-O device in the area of the sacrospinous ligament. As earlier indicated, in July 2021, Plaintiff underwent an excision surgery performed by Howard B. Goldman, M.D. *See* Urology Operative Report (ECF No. 157-3) (stating mesh came from the obturator nerve). Dr. Goldman confirmed that he removed two pieces of mesh and stated that the pathology report likely referred to one sample because the two pieces he removed were "clumped together." By the time the mesh specimen reached pathology, it appears only one specimen was in pathology. *See* Surgical Pathology Report (ECF No. 157-4). According to Plaintiff, the pathology does not make it clear from which part of the body the specimen was removed. Therefore, it is uncertain which device was removed and from which part of Plaintiff's body it was removed. Therefore, it is Plaintiff's position that any opinions with regarding where the mesh specimen was located in Plaintiff's body is speculative.

Dr. Mueller opines in her original report that the TVT-O sling was misplaced. *See* ECF No. 140-3 at PageID #: [15-16]. She reaches her conclusion by relying on the medical records and opinion of Dr. Ferrando that the sling was malpositioned because it was placed higher on the urethra than it should have been, while disregarding the testimony of Dr. Vassas. *See* ECF No. 140-8 at PageID #: [79:21-24]. Then, after Plaintiff's July 2021 surgery, Dr. Mueller attempted to bolster her previous opinion on malpositioning. *See* Supplemental Case Specific Expert

Report (ECF No. 188-1). Plaintiff argues that Dr. Mueller did this without knowing what kind of mesh the specimen is and from where it was removed.

This prong of Plaintiff's motion is denied. Dr. Mueller's opinion of the sling placement is based on the facts, including the pathology's indecision, that will be made known to the jury. That is not conjecture.

B.

Dr. Mueller opines about safer alternative designs in her original report. She states that the safer alternative designs that were offered by Dr. Rosenzweig in his report, *e.g.*, rectus fascial slings, Burch urethropexy procedures, and midurethral slings, "are not possible alternative designs to the TVT-O because they are types of medical procedures and not types of medical devices." ECF No. 140-3 at PageID #: 16715. Plaintiff argues this statement goes beyond the scope of Dr. Mueller's expertise.

Whether a design is an "alternative design" or an "alternative procedure" has been at issue in many pelvic mesh cases. *See, e.g.*, *Pizzitola v. Ethicon, Inc.*, No. 4:20-CV-2256, 2020 WL 6365545, at *5 (S.D. Tex. Aug. 31, 2020) (the court stated that "[p]roducts are not substantially different simply because they are comprised of different materials" in response to Defendants' argument that Plaintiff's proposed safer alternatives, including designs made from human and animal tissues, did not constitute safer alternative designs because they were not made from synthetic mesh); *Burris v. Ethicon, Inc.*, No. 3:20CV1450, 2021 WL 3190747, at *8-9 (N.D. Ohio July 28, 2021) (granting summary judgment on Plaintiff's design defect claim

under Ohio law because plaintiff failed to present evidence of an alternative design, but finding the analysis of whether an alternative design is a different "procedure" involves a legal question).

This prong of the motion is denied because Dr. Mueller is within her medical expertise to say if something is a procedure or not.

C.

Plaintiff argues Dr. Mueller jumps to further unsupported conclusions about Plaintiff's pain in her report by misinterpreting the significance of a pain journal Plaintiff kept while she was recovering from injuries she sustained in a motor vehicle collision. *See* ECF No. 140-3 at PageID #: [31]; *see also* ECF No. 140-2 at PageID #: [60:04-62:07] (clarifying her reliance on Plaintiff's journal). In contrast to Dr. Mueller's characterization of the journal at issue, Plaintiff made clear in her deposition that she kept the journal at the suggestion of her neurologist as a way to keep track of the concussive symptoms she experienced after the collision. *See* Deposition of Jane Olszeski (ECF No. 140-4) at PageID #: [74:02-20]. Despite Dr. Mueller's assertion that she read and reviewed Plaintiff's deposition testimony, her conclusion that Plaintiff must not have experienced vaginal, groin and thigh pain during the time period in question because she failed to mention it in her journal is unreliable and unsound because Dr. Mueller failed to account for (or even acknowledge) Plaintiff's explanation during her deposition. These criticisms of Dr. Mueller's conclusions regarding Plaintiff's pain are, nevertheless, more appropriately addressed on cross-examination than at the *Daubert* stage.

The same can be said of Dr. Mueller's opinions about Plaintiff's experts, Dr. Rosenzweig (*compare* ECF No. 140-3 at PageID #: [33] with ECF No. 92-6 at PageID #: [126-27] (thigh

liposuction)), Dr. Hibner (*compare* ECF No. 140-3 at PageID #: [37] with ECF No. 132-2 at PageID #: [18, 23] (when obturator neuralgia occurs), Dr. Ferrando (compare ECF No. 140-3 at PageID #: [41] with ECF No. 140-7 at PageID #: [38:11-17] (whether removal of TVT-O was "medically unnecessary"). These opinions would be a matter for cross-examination, not exclusion.

The same, however, cannot be said of Dr. Mueller's discussion of Plaintiff's social history. *See* ECF No. 140-3 at PageID #: 16709. This unrelated information is excluded because it is not relevant to her expert analysis.

D.

Finally, Dr. Mueller's Report discusses various position statements issued by various medical organizations, including AUGS, on TVM. *See* ECF No. 140-3 at PageID #: [40]. Many courts, including the MDL court, have repeatedly held that "position statements are not expert opinions." *Tyree v. Boston Scientific Corp.*, 54 F. Supp.3d 501, 574 (S.D.W.Va. 2014); *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp.3d 658, 720 (S.D.W.Va. 2014). Like the MDL court, the Court reserves ruling on this prong until trial.

III. ECF No. 137 - Shelby Thames, Ph.D.

Dr. Thames is a polymer chemist with a Ph.D. in organic chemistry and Defendants' material scientist in the case at bar. He served as a general expert during the MDL, in which he offered several opinions in defense of Ethicon's PROLENE-based meshes used by Ethicon to manufacture its SUI devices, including the TVT-O device that allegedly injured Plaintiff. He opines that it does not degrade after implantation into the human body. ECF No. 137-16 is his

General Report. ECF No. 137-19 is his case-specific report.[2] It states, "In conclusion, there are no data of which I am aware suggesting Prolene® in Ms. Olszeski's mesh degraded *in vivo*." ECF No. 137-19 at PageID #: 15602. The motion requests that the Court limit Dr. Thames' general and case-specific opinions. Sections A (the PROLENE used in Defendants' SUI mesh products undergoes *in vivo* degradation) and C (Dr. Thames cannot determine PROLENE's "toughness" from the tensile testing data collected from year 7 of Dan Burkley's dog study) of that motion are challenges to general opinions of Dr. Thames. Only the following case-specific portions will be addressed in this opinion.

A.

Plaintiff argues Dr. Thames' PROLENE-specific opinions in his case-specific expert report conflict with the available evidence (*see* ECF Nos. 137-1 through 137-13[3]), and furthermore, lack scientific support. According to Plaintiff, Dr. Thames needs scientific support to proffer his opinions, and he has provided nothing reliable to support his opinion that PROLENE does not degrade or that it remains inert inside the body. Plaintiff contends his expert report is at conflict with itself. Plaintiff claims the PROLENE-specific opinions described in his case-specific expert report (ECF No. 137-19) not only fail to grapple with the available scientific literature and Ethicon's 30(b)(6) corporate designee, Dr. Thomas Barbolt (*see* ECF No. 137-15 at

[2] Dr. Thames also submitted a supplemental opinion after the July 2021 excision surgery that "both mesh samples from July 13, 2021 contained Boston Scientific Pinnacle." ECF No. 202-13 at PageID #: [1]. The within motion does not challenge that report.

[3] Medical literature that from Plaintiff's position establishes that mesh degrades.

PageID #: [396:2-23]), but also contradict decades of internal reports and conclusions on how PROLENE's oxidation causes degradation, environmental stress cracking, losses in molecular weight, and losses in its mechanical properties after implantation. Plaintiff contends Dr. Thames offers no peer-reviewed support for his PROLENE opinions and instead, manipulates the findings from one of the internal studies that he cites (the seven-year dog study) to bolster his belief "that Ethicon's Prolene material used in its mesh products does not undergo meaningful or harmful degradation *in vivo*." ECF No. 137-16 at PageID #: [6, 173]. Contrary to Plaintiff's assertion, Dr. Thames's testing protocol has twice been subjected to peer review. In earlier iterations of his general report, he stated that the absence of molecular weight loss indicates the absence of degradation. But forced to revise his report for mischaracterizing the evidence, Dr. Thames now states in his general report (ECF No. 137-16) that the absence of *meaningful* molecular weight loss shows that no *meaningful degradation* occurred. Plaintiff maintains that a methodology this malleable cannot serve as an adequate foundation for reliable scientific opinion, and Dr. Thames' methodology is both inconsistent and applied in an *ad hoc* fashion.

According to Plaintiff, despite being admonished by the MDL court for mischaracterizing the dog study in his Wave 1 report, Dr. Thames continues to inject overbroad opinions in his case-specific expert report, stating that: "[Plaintiff] contend[s], *without scientific evidence*, Prolene degrades *in vivo* with concomitant cracking, loss of physical integrity and toughness, loss of molecular weight, embrittlement, and so forth." ECF No. 137-19 at PageID #: 15597. The seven-year dog study, however, states on the second page under the section entitled

"Conclusions" that "Degradation in PROLENE is still increasing," and that "[o]f the eight explanted ETHILON sutures all showed heavy cracking." ECF No. 137-13 at PageID #: 14687.

B.

Next, Plaintiff argues Dr. Thames' case-specific opinions on the presence of extrusion lines and translucent flakes on explanted mesh are unsupported and must be excluded for the following reasons. Any testimony about the presence of clear or colored flakes on explanted mesh, or about the presence of extrusion lines on explanted mesh, should be excluded. These opinions have no basis in the scientific method and no backing in the peer-reviewed literature – they are simply inadmissible *ipse dixit* opinions and need to be precluded. Dr. Thames opines that he sees translucent flakes on explanted blue fibers of PROLENE, and because they are translucent, he believes that they are protein and not degraded polypropylene. But, Dr. Thames cannot cite to any literature or support for that opinion. *See* Deposition of Shelby F. Thames, Ph.D. from the *Stubblefield* case (ECF No. 137-23) at PageID #: [47:3-48:18]. Dr. Thames also maintains these opinions about the extrusion lines in his case-specific report in the case at bar, stating: "For instance, the cleaned Prolene® fibers of Figure 4 continue to possess manufacturing created extrusion lines. If the surface of Prolene® fibers degrade in vivo, as postulated by [P]laintiff's experts, the extrusion lines, and thus the Prolene® fiber surface, would likewise degrade during this process and would no longer be essentially pristine. These data are additional evidence surface oxidation/degradation of the Olszeski Prolene® implant did not occur." ECF No. 137-19 at PageID #: [5]. According to Plaintiff, Dr. Thames' opinion that the extrusion lines would not be "essentially pristine" and would have degraded if surface

oxidation/degradation occurred is based entirely on speculation and constitutes textbook *ipse dixit*. Regardless of what Dr. Thames believes to be true, if he cannot substantiate or support those beliefs in any meaningful way, Plaintiff contends they should not be heard by the jury.

C.

Finally, Plaintiff argues Dr. Thames' opinions on the presence of extrusion lines and translucent flakes on explanted mesh are the tainted result of a flawed cleaning protocol, which renders all of his testing-related opinions unreliable. Plaintiff's position is that the data Dr. Thames collected and the opinions he proffers about extrusion lines and translucent flakes from that testing are of no significance. According to Plaintiff, his cleaning protocol renders any testimony about the plaintiff-specific examinations he performed in his case-specific report (ECF No. 137-19) unreliable. Dr. Thames opines that none of the mesh explants he examined showed signs of oxidation, but Plaintiff maintains his testing – and any related testimony – should be excluded because Dr. Thames would have destroyed any evidence of oxidation that existed on the mesh. Dr. Thames' protocol calls for up to 23 steps to be performed on the mesh samples he examined, including the use of Proteinase-K (a mild enzyme), sonication and shaking, water, heat and bleach – all of which could have destroyed evidence of surface oxidation. But Dr. Thames did not determine what effect, if any, the various steps of his cleaning protocol had on oxidized PROLENE. He assumed there would be none even though the peer reviewed literature going back as far as 1998 states that stresses like shaking and sonication removes the outer degraded layer from explanted PROLENE. *See* Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, *Comparison of the In Vivo*

Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) (ECF No. 137-3). Dr. Thames even explained at his deposition that one of the steps – the use of Proteinase-K – was intended to destroy the very evidence of oxidation that he was supposedly trying to find. *See* General Expert Deposition of Shelby F. Thames, Ph.D. from the MDL case (ECF No. 137-14) at PageID #: [61:16-62:9]. Even worse, according to Plaintiff, Dr. Thames did not run a control of purposefully oxidized polypropylene through any of the steps of his cleaning protocol to test if it would destroy evidence of oxidation on the mesh samples he examined. *See* Deposition of Shelby F. Thames, Ph.D. from the *Danno* case (ECF No. 137-24) at PageID #: [21:3-16]. Plaintiff contends what Dr. Thames did by employing this cleaning protocol was to "run a rigged game." ECF No. 137 at PageID #: 14562. According to Dr. Thames, Proteinase K strips carbonyls, but carbonyls are also what show oxidization of the mesh. *See* Affidavit of Shelby F. Thames, Ph.D. (ECF No. 147-9) at ¶¶ 10, 17. Also, he chose to employ sonication and shaking even though the peer reviewed literature explains that that is how you would remove the outer-degraded layer from explanted PROLENE. Plaintiff concludes that Dr. Thames' analysis would not have discovered evidence of mesh oxidation—because his cleaning protocol was destroying it.

Plaintiff's criticisms of Dr. Thames' conclusions are more appropriately addressed by confrontation and cross-examination than exclusion at the *Daubert* stage. ECF No. 137 is denied.

IV. ECF No. 135 - Bruce Rosenzweig, M.D.

Dr. Rosenzweig is a pelvic surgeon and urogynecologist. ECF No. 135-2 is his General Report. ECF No. 135-3 is his case-specific report. The motion requests that the Court limit his general and case-specific opinions. Sections II.A. (offering opinions that the MDL court has excluded), II.F. (criticizing Ethicon's collection and reporting of adverse events), and II.H. (testifying about the propylene resin MSDS sheet) of the motion are challenges to Dr. Rosenzweig's general opinions. Only the following case-specific portions will be addressed in this opinion.

A.

Defendants argue the Court should preclude Dr. Rosenzweig from testifying that nonsynthetic mesh surgeries are a safer alternative to TVT-O because they are not alternative products. They do not involve a different or alternative design, which is required under Ohio law.

To prove her design defect claims, Plaintiff must show the availability of a feasible safer alternative design. Ohio Rev. Code § 2307.75(F). Dr. Rosenzweig claims the Burch procedure (a traditional open abdominal surgical procedure that does not entail implanting a medical device), autologous slings (using the patient's own body tissues harvested from the inner thigh), and allograft slings (using donor tissue) lead to fewer complications than TVT-O for the surgical treatment of SUI and opines that they would have been safer alternatives for Plaintiff. *See* ECF No. 135-2 at PageID #: [108-109]; ECF No. 135-3 at PageID #: [28, 67]. According to Defendants, these alternatives are irrelevant because they are not alternative designs of TVT-O

that would improve TVT-O's design to make it safer. They, instead, contemplate TVT-O not being used at all.

> In *Burris v. Ethicon, Inc.*, the district court stated:
>
> > . . . Defendants contend Dr. Galloway's opinions on biologic alternatives such as allografts and xenografts are insufficient for Plaintiff to proceed with her [design defect] claim because . . . biologic alternatives do not qualify as an alternative design to polypropylene mesh products such as the TVT-S. . . . The Court finds Defendants' . . . argument dispositive. At base, the question is whether biologic alternatives can satisfy the standard for "a practical and technically feasible alternative design". Ohio Rev. Code § 2307.75(F). The MDL court explained "an alternative, feasible design must be examined in the context of products—not surgeries or procedures". *Mullins v. Johnson & Johnson*, 236 F. Supp.3d 940, 942 (S.D.W. Va. 2017). . . . Plaintiff points to no specific evidence – from Dr. Galloway or otherwise – explaining how Dr. Galloway's citation of "autologous grafts, allografts and xenografts" . . ., are a specific alternative design for the medical devices at issue here. Further, like many other courts have, this Court agrees with the above analysis from the MDL court and the *Willet* court regarding biologic alternatives, and alternative procedures. . . . [T]his Court thus finds that the "autologous grafts, allografts and xenografts" identified by Dr. Galloway cannot satisfy the "practical and technically feasible alternative design" required by Ohio Rev. Code § 2307.75(F) because, at base, they are not different designs for the medical product polypropylene mesh products at issue here, but rather completely different procedures subject to completely different regulations.

No. 3:20CV1450, 2021 WL 3190747, at *6-8 (N.D. Ohio July 28, 2021) (footnote omitted); *see also Simpson v. Johnson & Johnson*, No. 5:20-cv-1237, 2020 WL 5630036, at *3 (N.D. Ohio (Sept. 21, 2020). In addition, "[t]o introduce evidence of alternative surgical procedures in a product liability case is irrelevant and would create confusion for the jury." *Hosbrook v. Ethicon, Inc.*, No. 3:20-CV-88, 2021 WL 1599199, at *4 (S.D. Ohio Apr. 23, 2021). Finally, Dr. Rosenzweig has acknowledged that the Burch procedure and autologous slings are not even medical devices. 2015 Deposition (ECF No. 135-4); *but cf.* Deposition of Bruce A. Rosenzweig, M.D. (ECF No. 155-2) at PageID #: [82:1-9] (clarifying his position on this issue).

This prong of the motion is granted. *See Sexton v. Ethicon, Inc.*, No. 5:20-cv-282, 2021 WL 4138399, at *6 (E.D. Ky. Sept. 10, 2021) ("Courts considering the use of biologic slings, or similar products and procedures that do not use mesh, have found that such products and procedures fail to show a feasible, safer alternative design because they are not, in fact, alternative designs to mesh products.").

B.

Next, Defendants argue the Court should preclude Dr. Rosenzweig from testifying that a device with a different type of mesh would be a safer alternative to TVT-O for the surgical treatment of SUI.

Under Ohio law, evidence of a safer alternative design is only relevant if it was "technically feasible" and "available" and it "would have prevented" the harm alleged. Ohio Rev. Code § 2307.75(F). Dr. Rosenzweig opines that a "sling with less polypropylene such as Ultrapro" would have been a safer alternative for Plaintiff. ECF No. 135-3 at PageID #: [67-68]. Defendants argue this opinion is irrelevant because (a) no such product was available at the time of Plaintiff's implant to treat SUI; (b) Plaintiff has no expert proof that such a product was feasible; and (c) Rosenzweig has testified that any such hypothetical product would not have eliminated the risks presented to Plaintiff. No sling with Ultrapro (or another alternative suggested by Rosenzweig) has ever been cleared by the FDA and made available even to this date. *See Willet v. Johnson & Johnson*, 465 F. Supp.3d 895, 901, 907-09 (S.D. Iowa 2020) (precluding plaintiff's expert from testifying that a device with Ultrapro mesh was a safer alternative because it was never FDA-approved and launched); *Wood v. Am. Med. Sys. Inc.*, 2021

WL 1178547, at *1, 10 (D. Colo. Mar. 26, 2021) (precluding Dr. Rosenzweig from offering these same opinions and finding that "testimony about Dynamesh and Ultrapro is inadmissible because neither is available to American patients"). Nor can Plaintiff present competent evidence that it would have been feasible to develop a TVT-O with Ultrapro. Ethicon attempted to develop a product to treat SUI with Ultrapro, but it failed cadaver testing. A Kentucky federal court recently found that similar opinions by Dr. Rosenzweig were irrelevant and that his report did not reliably demonstrate that a device with Ultrapro would have been feasible. *Thacker v. Ethicon, Inc.*, No. 5:20-cv-0050-JMH-MAS, 2021 WL 5362076, at *10 (E.D. Ky. Nov. 17, 2021). Finally, even if Plaintiff had competent expert proof that a TVT-O with Ultrapro was available and feasible at the time of Plaintiff's implant, Rosenzweig's opinion is irrelevant and inadmissible because, at his deposition, he conceded that such a hypothetical device would have only reduced – but not eliminated – the pertinent risks posed to Plaintiff. *See* Excerpts from Deposition of Bruce A. Rosenzweig, M.D. (ECF No. 135-6) at PageID #: [156:17-157:5, 161:7-10].

Consistent with the Court's recent ruling on Defendants' Motion *in Limine* No. 9, *see* Transcript of Proceedings (ECF No. 282) at PageID #: 44185, this prong of the motion is denied. Dr. Rosenzweig will be permitted to offer Ultrapro as a substitute and the feasibility of its use is better suited to cross-examination at trial. *See Terry v. Ethicon, Inc.*, 1:19-CV-00175-GNS, 2022 WL 468051, at *6 (W.D. Ky. Feb. 15, 2022); *Sexton*, 2021 WL 4138399, at *6; and *Williams v. Ethicon, Inc.*, No. 1:20-cv-04341-SDG, 2021 WL 857747, at *6 (N.D. Ga. March 8, 2021).

C.

Defendants contend the Court should preclude Dr. Rosenzweig from testifying that a retropubic sling, such as TVT, would have been a safer alternative to the TVT-O for the surgical treatment of SUI.

This polypropylene mesh sling is similar to the TVT-O, but inserted through a different route of placement – the retropubic route. Although a retropubic sling was feasible and available, Dr. Rosenzweig testified that such a device is also defective and would have merely reduced, but not eliminated, the risk of harm. *See* ECF No. 135-6 at PageID #: [152:12-14; 153:17-154:16]. That is a point for cross-examination and not a proper basis for exclusion. Dr. Vassas had the option to implant Plaintiff with a TVT and chose not to do so. Thus, treating doctor's decision to choose one device (TVT-O) over another available device (retropubic sling) does not speak to an alternative design for the product, but instead to the doctor's treatment choice. *See Burris*, 2021 WL 3190747, at *8.

Plaintiff argues Defendants misconstrue the current state of the law and the requirements of the law as it pertains to the "prevented the harm" requirement of Ohio Rev. Code § 2307.75(F). *See Rheinfrank v. Abbott Laboratories, Inc.*, 137 F. Supp.3d 1035, 1040 (S.D. Ohio 2015) (holding that the Court had earlier "misconstrued" Plaintiffs' burden in coming forward with evidence of an alternative design that "prevented" the harm in the context of an antiepileptic drug). "The phrase 'would have prevented the harm' within the state-of-the-art provision, [in the New Jersey Products Liability Act], logically must be read to mean 'prevented the degree of harm' caused by the defendant's product, rather than total elimination of risk. Virtually all products have some inherent risk of harm. If we were to read the state-of-the-art

provision as defendants here suggest and require plaintiffs to posit risk-free alternatives, that could eviscerate strict liability in design defect cases." *Hrymoc v. Ethicon, Inc.*,Nos. A-5151-17, A-1083-18, 2021 WL 836854, at *34 (N.J. App. Div. (March 2, 2021). Plaintiff has provided testimony from Dr. Rosenzweig that the retropubic sling constitutes a safer alternative design because it would have eliminated her risk of obturator neuralgia considering it would not impact the obturator externus muscle. *See* ECF No. 155-2 at PageID #: [153:21-154:7]. The retropubic mid-urethral sling was available and on the market at the same time as the TVT-O was implanted in Plaintiff, and was sold as the Gynecare TVT device. Unlike the legal elements required for Plaintiff's failure to warn claim, the thoughts and actions of the implanting physician are irrelevant to a proposed safer alternative design. Plaintiff argues Ethicon has deceived the medical community, including Dr. Vassas, regarding the risks and dangers of its TVT-O device and now seeks to benefit from this deception by leveraging Dr. Vassas' decision to implant that device to exclude Dr. Rosenzweig's opinions. Notably, the MDL Court, the Fourth Circuit, and at least one district court in the Eleventh Circuit have all agreed that a retropubic sling is an acceptable safer alternative design to a transobturator sling, like the TVT-O. *See Campbell v. Boston Scientific Corp.*, 882 F.3d 70, 79 (4th Cir. 2018); *Ellerbee v. Ethicon, Inc.*, No. 8:20-cv-1514-T-60AEP, 2020 WL 4815818, at *3 (M.D. Fla. Aug. 19, 2020).

This prong of the motion is denied.

D.

According to Defendants, the Court should preclude Dr. Rosenzweig from criticizing the manner by which TVT-O mesh is cut.

TVT-O contains mesh that is either mechanically-cut or cut using a laser. The mesh in Plaintiff's TVT-O was mechanically-cut. In the case at bar, Rosenzweig has criticized both ways in which the mesh is cut. Neither Rosenzweig nor any other expert has opined that Plaintiff sustained any injury as a consequence of the way that the mesh was cut. Rosenzweig criticizes the only two ways that the mesh in TVT-O is cut and he does not suggest that any alternative to those two ways would be safer. He testified during his deposition that the cut of the mesh did not matter to opinion :

> Q. . . . Do you know whether Ms. Olszeski's TVT-O was laser cut or mechanically cut?
>
> A. I don't specifically recall the product sticker.
>
> Q. Does the cut of the mesh in this case factor into your opinions whatsoever?
>
> A. In this case, no.

ECF No. 155-2 at PageID #: [131:8-14].

This prong of the motion is denied because the manner by which TVT-O mesh is cut still has relevance to the jury's risk utility analysis. *See, e.g.*, *Foster v. Ethicon, Inc.*, No. 4:20-CV-04076-RAL, 2021 WL 4476642, at *11 (D.S.D. Sept. 30, 2021) (rejecting unreliability arguments pertaining to Dr. Rosenzweig's opinions regarding mechanical-cut and laser-cut mesh and holding that such arguments were a subject of cross-examination, not exclusion).

E.

Defendants argue Dr. Rosenzweig's opinions about the efficacy or the adequacy of Ethicon's warnings and his critique of Plaintiff's informed consent process should be excluded.

According to Defendants, Dr. Rosenzweig's opinions criticizing Ethicon's warnings of the risks associated with TVT-O do not fit the facts of the case at bar and should be excluded. They also contend the Court should not allow Rosenzweig to speculate about how Dr. Vassas navigated the informed consent process with Plaintiff. *See* ECF No. 135-3 at PageID #: 14219 ("Ms. Olszeski's implanting surgeon could not pass this information on to her and properly consent her about the risks associated with the TVT-O and Pinnacle devices."). Dr. Vassas testified, however, that she did not even rely on the instructions for use ("IFU")[4] to inform herself of risks related to this surgery, but instead, on her personal experience. *See* Excerpts from Deposition of Melissa Vassas, D.O. (ECF No. 135-9) at PageID #: [134:10-135:6, 226:4-9]. The MDL Court has consistently precluded Rosenzweig and others from offering these exact same opinions. *See, e.g.*, *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493457, at *3 (S.D. W.Va. Aug. 25, 2016); (precluding expert from testifying about "what physicians know or should know about specified topics"). More recently, in the *Taxotere* MDL, the court similarly precluded a plaintiff's expert from speculating about how a reasonable physician would have navigated the informed consent process given that the plaintiff's actual treating physician was available to testify. *In re: Taxotere (Docetaxel) Prods. Liab. Litig.*, MDL No. 16-2740, 16-17144, 2019 WL 3554211, at *2 (E.D. La. Aug. 5, 2019); *see also McBroom v. Ethicon, Inc.*, No. CV-20-02127-PHX-DGC, 2021 WL 2709292, at *11-12 (D. Ariz. July 1, 2021) (finding plaintiff did not explain how the adequacy of the IFUs and product warnings are

[4] A little package insert that comes in every box of TVT-0.

relevant to the remaining claims after granting summary judgment on plaintiff's failure to warn claim).

In response, Plaintiff argues Dr. Rosenzweig's opinions concerning the insufficiency of the TVT-O warnings are relevant to Plaintiff's failure to warn claims and should be permitted for those purposes. Such evidence also goes directly to Plaintiff's design defect claim and the factors to be considered when determining the foreseeable risks associated with the design of the TVT-O under Ohio Rev. Code §2307.75(B)(1). Defendants argue that Dr. Rosenzweig's "opinion is based on the false premise that the sole source of Vassas' knowledge of the risks of TVT-O is what is set forth in the product's instructions for use." ECF No. 135 at PageID #: 14036. No one, however, has argued that the sole source of Dr. Vassas' knowledge of the risks of the TVT-O is that set forth in the IFU. Dr. Vassas testified in her deposition that: (1) she read the TVT-O IFU prior to the time of Plaintiff's implantation surgery (ECF No. 155-4 at PageID #: [190:1-4]); (2) she believed the information contained in the IFU was "complete and truthful and accurate" (ECF No. 155-4 at PageID #: [190:5-8; 192:24-193:3]); and (3) the IFU was intended for her benefit and she would sometimes provide it to her patients (ECF No. 155-4 at PageID #: [192:15-23]). Dr. Rosenzweig's opinions concerning what information Ethicon provided the medical community at large (including Dr. Vassas) regarding the risks of the TVT-O device, based upon his review of Ethicon internal documents, his understanding of the published medical literature at the time of Plaintiff's implantation procedure, the testimony of Dr. Vassas, and his own experience as a member of that medical community – provide a relevant backdrop against which the jury can evaluate Plaintiff's failure to warn claims.

This prong of the motion is denied because these opinions will assist the trier of fact in evaluating Plaintiff's design defect and failure to warn claims. The Court, however, will not allow Dr. Rosenzweig to testify about what the implanting physician knew or did not know as that should be left to a jury. *See, e.g.*, *Nall v. C. R. Bard, Inc.*, No. 2:13-CV-01526, 2018 WL 524632, at *2 (S.D.W. Va. Jan. 23, 2018) ("The defendant argues that I should preclude Dr. Rosenzweig from testifying as to the state of mind of the plaintiff and Dr. Foster, her implanting physician. I agree; experts may not testify about what other parties did or did not know.").

F.

Finally, Defendants contend the Court should preclude Dr. Rosenzweig from testifying about mesh degradation.

Although Rosenzweig opines that the mesh in Plaintiff's TVT-O degraded, *see, e.g.*, ECF No. 135-3 at PageID #: [66], the report from Dr. Shih, Plaintiff's case-specific pathology expert, does not indicate that the mesh in her TVT-O degraded. *See* ECF No. 135-10. In addition, Defendants argue, this is an area beyond Dr. Rosenzweig's expertise as a urogynecologist.

Dr. Rosenzweig's opinion that polypropylene mesh is capable of degradation is based upon his review of the medical and scientific literature, the expert reports of polymer scientist Jimmy Mays, Ph.D., materials scientist Scott A. Guelcher, Ph.D., and general pathologist Dr. Vladimir Iakovlev, Ethicon's own internal documents and testing data, and testimony from Ethicon employees, including Ethicon scientist Daniel Burkley. *See* ECF No. 155-3 at PageID #: [12-19]; ECF No. 155-5 at PageID #: [7]. Moreover, in his years of experience explanting mesh from patients, Dr. Rosenzweig has "personally seen mesh that is broken, cracked and looks

different from when it came out of the package." ECF No. 155-3 at PageID #: [18]. Rosenzweig's lack of background in biomaterials or his absence of a degree in polymer chemistry is immaterial to such opinions. Finally, if Defendants take issue with the data and materials upon which Dr. Rosenzweig relies for his degradation opinions, that is a topic of cross-examination, not a basis for exclusion, and goes to the weight and credibility of his opinions, not their admissibility.

Rosenzweig does not rely upon Dr. Shih's expert report, which does not indicate that the mesh in her TVT-O degraded. Dr. Shih does, however, make a finding of "birefringence," that Rosenzweig applies. *See Sexton*, 2021 WL 4138399, at *8 (permitting Dr. Rosenzweig to offer his opinion on alleged evidence of degradation) (citing *Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *5 (S.D. W.Va. May 5, 2015).

This prong of the motion is denied.

V. ECF No. 132 - Michael Hibner, M.D., Ph.D.

Dr. Hibner's report states "Ms. Olszeski's primary disabling conditions are right and left pudendal neuralgia and right and left obturator neuralgia," which "more likely than not [is] caused by one factor which in this case is the TVT-O sling[.]" Rule 26 Expert Report of Michael Hibner, MD, Ph.D. (ECF No. 132-2) at PageID #: 13692. At deposition, however, Dr. Hibner confessed, "I don't know if I can really separate which of the meshes [did] that . . . . When you have two meshes implanted at the same time . . . it is impossible to tell which mesh did what." Remote Deposition of Michael Hibner, M.D. (ECF No. 132-3) at PageID #: [125; 128]; *see also* [133] (Q. . . . Other than the lack of clitoral sensation, you can't distinguish which mesh caused

any of the pudendal neuralgia symptoms, true? A. True.) According to Defendants, Dr. Hibner's opinions as to the TVT-O's role in Plaintiff's injuries are unreliable, speculative, and should be excluded.

A.

Defendants argue Dr. Hibner is unable to opine that Plaintiff's TVT-O proximately caused her injuries with the certainty required by Ohio law. Given the "impossib[ility]" of "tell[ing] which mesh did what," ECF No. 132-3 at PageID #: [128], any opinion by him purporting to do so necessarily constitutes unreliable and inadmissible speculation. *See Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010) ("[A] plausible hypothesis [, which] may even be right[,] . . . is [still] no more than a hypothesis, and it thus is not 'knowledge,' nor is it 'based upon sufficient facts or data' or the 'product of reliable principles and methods . . . applied . . . reliably to the facts of the case.' ") (quoting Fed. R. Evid. 702). Defendants claim, at a minimum, Dr. Hibner should be precluded from opining that Plaintiff's TVT-O proximately caused her pudendal neuralgia because he repeatedly testified that, in fact, "Pinnacle mesh . . . is the mesh that is more likely to cause pudendal neuralgia." ECF No. 132-3 at PageID #: [125]; *see also* [126] ("[S]he has . . . two different neuralgias and two different meshes and it's likely that one caused one pain and the other caused the other pain."). Hibner also testified that all Plaintiff's symptoms, other than groin pain, "are due to pudendal neuralgia." ECF No. 132-3 at PageID #: [130]. Therefore, Defendants contend Dr. Hibner should likewise be precluded from opining that Plaintiff's symptoms, other than groin pain, were caused by her TVT-O.

In response, Plaintiff argues that understood in full, Dr. Hibner's deposition testimony makes clear that the TVT-O proximately caused Plaintiff's injuries – indeed he attributes the TVT-O to her injuries even more so than the Pinnacle mesh at issue. In addition, Dr. Hibner testified that the TVT-O and the Pinnacle likely both contributed to pudendal neuralgia in Plaintiff, and the TVT-O contributed more to her obturator neuralgia. *See* ECF No. 132-2 at PageID #: [122:20-124:17; 125:01-25; 126:05-128:21].

This prong of the motion is denied. To the extent there are conflicts or inconsistencies in Dr. Hibner's deposition testimony, those may be the subject of cross-examination for the jury's consideration and are not a basis for exclusion.

B.

Dr. Hibner opines (1) that Plaintiff's TVT-O shrunk or contracted, ECF No. 132-2 at PageID #: [47] ("This portion appeared under tension and contracted."), [48] ("The anterior vaginal wall was palpated and her prior sling was felt to be on contracted, twisted and under tension."), [70] ("I have encountered mesh that is slightly twisted and under tension . . ."), and (2) that those alleged "defects" proximately caused her injuries. According to Ethicon, his opinions that the TVT-O had a design defect that proximately caused Plaintiff's injuries lack an adequate or reliable foundation. Rather they are only speculation. The alleged "defects" in Plaintiff's TVT-O to which Dr. Hibner purports to attribute Plaintiff's injuries are "degradation [and] shrinkage of the device." Defendants argue Hibner lacks "sufficient facts or data" to reliably opine that either of these phenomena occurred in Plaintiff's TVT-O and caused her injuries. Fed. R. Civ. P. 702(b); *see also Burris v. Ethicon, Inc.*, No. 3:20CV1450, 2021 WL

3190747, at *9 (N.D. Ohio July 28, 2021) ("Courts should confirm 'the factual underpinnings of the expert's opinion [are] sound.' ") (quoting *Greenwell v. Boatwright*, 184 F.3d 492, 498 (6th Cir. 1999)); *Pogue v. Nw. Mut. Life Ins. Co.*, No. 3:14-CV-00598, 2017 WL 4227657, at *5 (W.D. Ky. Sept. 22, 2017) (excluding expert opinion). The parties agree that Hibner admits in his deposition that there is no objective medical evidence – be it imaging, his own observation, pathology samples or reports, or any other medical record – that Plaintiff's mesh implant shrunk or degraded. *See* ECF No. 173 at PageID #: 20871. Indeed, Dr. Rosenzweig, another of Plaintiff's case-specific experts, identifies multiple other alleged defects and mechanisms he opines can cause injuries like Plaintiff's.

Plaintiff notes that Dr. Hibner testified that not only degradation and shrinkage, but also inflammation and scarification, were the design defects inherent to the TVT-O device. *See* ECF No. 132-2 at PageID #: [81:10-18; 82:19-83:09]. Dr. Hibner explained his inflammation and scarring opinions in full. *See* ECF No. 132-2 at PageID #: [18, 23, 36]. Defendants contend, however, that inflammation and scarification are complications that Plaintiff experienced. They maintain Dr. Hibner's opinions about defect and the defective design of the product relate to his opinions about degradation and shrinkage. And so opinions beyond those two with respect to defects should be excluded.

This prong of the motion is denied.

C.

Mesh degradation and shrinkage are the only alleged defects Hibner purports to link to Plaintiff's injuries. Opinions about complications not experienced by Plaintiff and alleged

defects that did not contribute to her injuries are irrelevant and lack foundation under Rule 702. Hibner should be precluded from opining about any other alleged mesh-related complications, including but not limited to autoimmune disorders, because "[e]vidence of complications that the plaintiff did not experience is irrelevant and lacking in probative value." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at *5 (S.D. W.Va. Aug. 26, 2016).

D.

"Under Ohio design defect law, a plaintiff must prove 'a practical and technically feasible alternative design' to the product at issue was available." *Burris*, 2021 WL 3190747, at *5 (quoting Ohio Rev. Code. § 2307.75(F)). In addition, in medical device cases like the case at bar, a design defect claim requires "expert testimony that [the] feasible alternative design would have prevented the harm." *Hutchens v. Abbott Lab'ys, Inc.*, No. 1:14CV176, 2016 WL 5661582, at *4 (N.D. Ohio Sept. 30, 2016). The only purported "safer alternative design" to TVT-O Hibner identifies in his report "is the retropubic sling," including "the Ethicon TVT retropubic." Defendants argue Dr. Hibner does not believe the purported safer alternative design to TVT-O he identifies is reasonably safe, did not opine that it would have prevented Plaintiff's injuries, and cannot offer admissible opinions regarding other alternatives.

Defendants claim Dr. Hibner should be precluded from opining that retropubic slings are a safer alternative design to TVT-O for two reasons. First, although Hibner believes retropubic slings like TVT are "safer" than TVT-O, he testified that "in no way am I saying [the retropubic]'s safe." Second, and in any event, Hibner does not opine that a retropubic sling

"would have prevented" Plaintiff's injuries as required by Ohio Rev. Code § 2307.75(F). The Court should exclude Hibner's opinion that "the retropubic sling" was a safer alternative design to TVT-O.

At deposition, Hibner "sought to expand his view on alternative designs" by raising Ultrapro or biologic allograft slings as possible alternatives. According to Defendants, Hibner should also be precluded from opining about any other purported alternatives designs. *See* Fed. R. Civ. P. 37(c)(1).

For the reasons set forth above in Section IV with regard to Dr. Rosenzweig, this prong of the motion is granted in part and denied in part. *See Sexton*, 2021 WL 4138399, at *6 ("Courts considering the use of biologic slings, or similar products and procedures that do not use mesh, have found that such products and procedures fail to show a feasible, safer alternative design because they are not, in fact, alternative designs to mesh products."). Dr. Hibner, however, will be permitted to offer Ultrapro and retropubic slings as substitutes and the feasibility of their use is better suited to cross-examination at trial. *See Terry*, 2022 WL 468051, at *6; *Sexton*, 2021 WL 4138399, at *6; and *Williams*, 2021 WL 857747, at *6; *Campbell*, 882 F.3d at 79; *Ellerbee*, 2020 WL 4815818, at *3.

E.

Defendants argue Dr. Hibner's warning opinions are irrelevant, constitute impermissible legal conclusions, and go beyond his qualifications as a urogynecologist. Citing *Simpson*, Defendants contend Dr. Hibner's "opinion that the defendants' warnings were inadequate is not relevant because it is undisputed that Dr. [Vassas], the person to whom defendants' owed a duty

to warn, knew of the risk of those injuries." 2020 WL 5630036, at *4. The Rules "requir[e] exclusion of expert testimony that expresses a legal conclusion." *Berry v. City of Detroit*, 25 F.3d 1342, 1353 (6th Cir. 1994) (quoting Fed. R. Evid. 704(a)). The Court should exclude Dr. Hibner's opinion that the "Ethicon TVT-O warning is not adequate" as an impermissible legal conclusion. Finally, any opinion by Dr. Hibner regarding what should or should not have been included in the TVT-O IFU should be excluded as beyond his qualifications. Like the expert in *Burris*, Defendants argue Dr. Hibner lacks "additional expertise regarding the drafting of IFU documents" and, therefore, should "not be permitted to testify as to what warnings are required to be included in an IFU." 2021 WL 3190747, at *12.

This prong of the motion is denied for the reasons set forth above in Section IV with regard to Dr. Rosenzweig. These opinions will assist the trier of fact in evaluating Plaintiff's design defect and failure to warn claims. The Court, however, will not allow Dr. Hibner to testify about what the implanting physician knew or did not know, as that should be left to a jury. *See, e.g.*, *Nall*, 2018 WL 524632, at *2.

F.

Dr. Hibner opines in his report that "[d]epression and any other psychological distress that Ms. Olszeski suffers is the direct result of pudendal neuralgia," which he attributes to her mesh implants. Defendants argue he is not qualified to opine about the cause of Plaintiff's depression or other psychological distress. Whether Dr. Hibner is qualified to diagnose depression or other mental health conditions, Defendants claim he is manifestly and admittedly unqualified to reliably opine as to the specific cause(s) of such conditions. Even if Dr. Hibner

were qualified to opine about the cause(s) of Plaintiff's mental health conditions, Defendants note he did not perform a differential diagnosis, much less a reliable one, to reach his opinion. *See* Fed. R. Civ. P. 702; *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670-75 (6th Cir. 2010).

In response, Plaintiff points out that Dr. Hibner, whom specializes in the treatment of pelvic pain and vaginal mesh complications, testified about "depression and other psychological symptoms" at length in his deposition. According to Plaintiff, Dr. Hibner demonstrated his qualifications to opine as such in his Report. *See* ECF No. 132-2 at PageID #: [69]. The opinions and qualifications stated in his report, taken together with his deposition testimony and that of Plaintiff, *see* ECF No. 173-5 at PageID #: [43:10-24], provides a reliable foundation for Dr. Hibner's depression and other psychological prognoses.

This prong of the motion is denied. Dr. Hibner's opinions about the cause of Plaintiff's depression or other psychological distress are more appropriately addressed on cross-examination.

G.

Dr. Hibner lists nine purportedly "medically necessary treatments" he claims Plaintiff will "require" in the future. *See* ECF No. 132-2 at PageID #: [70-71]. Defendants argue that Dr. Hibner's future care opinions exceed his expertise, do not meet the applicable standards under Ohio law, and are conclusory, speculative, and lack foundation. First, [Dr.] Hibner admits that "[p]erforming an Impairment Rating is outside my clinical expertise." Second, Dr. Hibner's "[f]uture care" opinions do not meet the applicable standards under Ohio law. Third, Dr.

Hibner's opinions regarding future care are conclusory, speculative and lacking an adequate or reliable foundation.

Dr. Hibner offered his future prognosis and treatment opinions to Plaintiff's life care planner, Dr. Leigh Anne Levy, who used that in formation in her telephonic consultation with Dr. Hibner (along with Dr. Rosenzweig) to come to her determination of likely future care necessary for Plaintiff. First, Ohio law does not regard expertise in Impairment Ratings as a requirement for opinion on future prognosis, treatment and care, and Defendants fail to cite any source to the contrary. Second, Dr. Hibner's opinions comply with Ohio law requiring future damages to be "reasonably certain to result." *See* ECF No. 132-2 at PageID #: [70-71]. Even though plaintiffs like Ms. Olszeski will likely never be "cured" or "fixed," treatments exist which seek to decrease or manage the resulting chronic, life-altering pain. Finally, any criticisms of Dr. Hibner's conclusions regarding future prognosis, treatment and care are more appropriately addressed on cross-examination than *via Daubert*.

VI. ECF No. 134 - Ie-Ming Shih, M.D., Ph.D.

Dr. Shih is Plaintiff's designated pathology expert. Defendants do not challenge his Report dated March 23, 2021 (ECF No. 134-3). The within challenges are to Dr. Shih's Supplemental Report (ECF No. 134-5), served on November 4, 2021, that provides a "causation" opinion. He reviewed tissue slides containing mesh that was removed during surgeries in October 2019 and July 2020, and his pathologic findings from his review of such slides are set forth in his initial report (ECF No. 134-3). Defendants do not dispute that the product contained in the slides from the 2019 and 2020 surgeries is TVT-O. Dr. Shih also performed a microscopic

analysis of tissue slides from Plaintiff's July 2021 mesh removal surgery and summarized his pathologic findings in ECF No. 134-5. Dr. Shih opines that "the three specimens from 2019, 2020, and 2021 show a consistent pattern of unresolved pathological issue[s] due to mesh [implantation] including chronic inflammation and fibrosis[,]" and that, "[i]f the patient manifests clinical symptoms including pain and others, these findings serve [as] the tissue evidence to explain her clinical problems." ECF No. 134-5 at PageID #: [2].[5]

ECF No. 134-5 does not, however, indicate which product was contained in the slides Dr. Shih reviewed from Plaintiff's July 2021 surgery, nor does it indicate that he reviewed any of Plaintiff's medical records, including records from the 2021 surgery. Defense experts also reviewed and analyzed specimens from Plaintiff's July 2021 surgery, as well as Plaintiff's medical records. Both experts (materials science expert, Dr. Shelby Thames, and pathology expert, Dr. Juan Carlos Felix) determined the mesh removed from the July 2021 surgery was not Ethicon's TVT-O product.

Defendants rely on the Case Specific Report of Shelby F. Thames, Ph.D. (ECF No. 134-7), in which he concludes "[t]he images below are a comparison of the Ethicon control and explant samples demonstrating the samples received are not Ethicon products." ECF No. 134-7 at PageID #: [2]. Figure 2 in the Report is a photograph of what Dr. Thames saw when he reviewed the July 2021 pathology. Figure 2a is a photograph entitled "TVT Control," which is

[5] The Court entered an Order (ECF No. 103) granting the parties' Joint Motion for Modification of Case Deadlines that provided Defendants an opportunity to request Dr. Shih's supplemental deposition on his supplemental report. But, they chose not to do so.

an exemplar of what a TVT-O looks like. Figure 2b is a photograph after the pathology from the 2021 procedure was cleaned. This is what was actually explanted from Plaintiff during that procedure and what Dr. Shih also reviewed. Figure 2c is a photograph of a second specimen from the 2021 procedure that was reviewed by Dr. Thames. Defendants also rely on the Supplemental Expert Report of Juan C. Felix, M.D. (ECF No. 134-8), in which he concludes "[t]he mesh fibers are of a size and configuration that is not consistent with a TVT-O sub urethral sling. In addition, there is no evidence of blue granules, typical of those contained in the individual blue Prolene mesh fibers that contribute to the composition of TVT-O." ECF No. 134-8 at PageID #: [3-4]. Therefore, Defendants claim Dr. Shih's opinions as to the July 2021 procedure don't "fit" the facts of the case at bar.

Defendants argue the Court should preclude Dr. Shih from offering any opinions or testimony correlating his pathological findings with Plaintiff's alleged clinical complications, including any opinion that the TVT-O caused such complications.

A.

According to Defendants, Dr. Shih's opinions and testimony based upon his review of tissue slides from Plaintiff's July 2021 surgery should be excluded as irrelevant, unreliable, and not helpful to the jury. Defendants argue that any opinions or testimony regarding Dr. Shih's pathologic findings on review of tissue slides from the July 2021 surgery should be excluded because the mesh contained in such slides is not from the TVT-O. Any opinions or testimony attributing the pathological findings set forth in ECF No. 134-5 to the TVT-O would be

inherently speculative and unreliable because Plaintiff underwent implantation of a Pinnacle mesh device during the same 2009 surgery in which the TVT-O was implanted.

According to Plaintiff, Defendants' attack on the relevance or "fit" of Dr. Shih's supplemental opinions rests on a factual dispute over the identity of the mesh in the pathology sample produced by the Cleveland Clinic. The jury is not bound to accept or believe the testimony of Defendants' experts – which has yet to be tested by cross-examination – and on this record, the identity of the mesh in the sample remains disputed. Plaintiff argues any ruling excluding Dr. Shih's findings from his review of the July 2021 sample for want of "fit" would be inappropriate and premature because it would require the Court to resolve this fact dispute. "When facts are in dispute, experts sometimes reach different conclusions based on competing versions of the facts," and a trial court should not "exclude an expert's testimony on the ground that the court believes one version of the facts and not the other." Fed. R. Evid. 702, advisory committee's note to 2000 amendment. At most, Defendants have identified grounds for cross-examination of Dr. Shih – not exclusion of his testimony under Rule 702. Like its attack on "fit," Defendants' attack on reliability at most raises an issue that goes to the weight of Dr. Shih's supplemental opinion – not its admissibility.

This prong of the motion is denied because fact issues exist concerning which manufacturer's mesh the July 2021 pathology sample contains. The jury will not only consider the testimony of Drs. Shih, Thames, and Felix, but also the operative report (ECF No. 157-3) and Surgical Pathology Report (ECF No. 157-4) from the July 2021 surgery, as well as Dr.

Goldman's statements that he removed two pieces of mesh and the pathology report likely referred to one sample because the two pieces he removed were "clumped together."

B.

Next, Defendants argue Dr. Shih's opinions regarding the cause of Plaintiff's alleged clinical complications should be excluded as untimely and unreliable. According to Defendants, even a cursory review of Dr. Shih's expert reports and deposition testimony makes clear that he has no reliable basis to offer opinions on the cause of Plaintiff's clinical symptoms. Indeed, he does not even know what those clinical symptoms are. *See* Deposition of Ie-Ming Shih, M.D. (ECF No. 134-4) at PageID #: [91:16-20]. Defendants contend any opinion that Plaintiff's clinical symptoms were caused by the TVT-O or correlating his pathological findings to her alleged clinical symptoms and injuries, is unreliable and speculative *ipse dixit*. Additionally, Dr. Shih's complications opinions as they relate to the tissue slides from Plaintiff's mesh removal surgeries in 2019 and 2020 should be excluded as untimely because he did not disclose any such opinions in his original report (ECF No. 134-3). Furthermore, such opinions are improper because Dr. Shih testified at deposition that he would not be offering any opinion at trial on the cause of Plaintiff's alleged clinical complications, including any opinion correlating his pathological findings with her alleged clinical symptoms. *See* ECF No. 134-4 at PageID #: [91:21-92:13].

In response, Plaintiff argues Dr. Shih timely disclosed his well-founded opinions about the significance of the findings in the 2019, 2020 and 2021 tissue samples. Exclusion of expert testimony based on failure to timely comply with the disclosure requirement of Fed. R. Civ. P.

26(a) is governed by Fed. R. Civ. P. 37(c)(1) and is not appropriate when the non-disclosure was substantially justified or harmless. *See Roberts v. Galen of Va., Inc.*, 325 F.3d 776, 782 (6th Cir. 2003) (holding non-disclosure harmless where counsel for the opposing party "knew who was going to testify and to what they were going to testify"). To the extent that Dr. Shih identified a "pattern" of unresolved pathology issues, he was justified in forming such opinion and promptly disclosing it only after evaluating the sample from a third mesh removal procedure. As for Dr. Shih's opinion that tissue samples exhibit pathology findings that could be correlated with clinical symptomology by a gynecologist familiar with Plaintiff's symptoms, Dr. Shih freely discussed this issue in his June 2021 deposition in connection with the samples taken in 2019 and 2020. *See* ECF No. 157-2 at PageID #: [88:1-15; 91:12-15; 92:2-4; 112:20-113:5]. Dr. Shih explained at that time that he did not believe the mesh in the slides was "inert," by which he meant that it "induced tissue inflammation or fibrosis and also caused the patient to have symptoms." ECF No. 157-2 at PageID #: [72:21-22, 73:5-7; 122:23-25]. Dr. Shih has simply explained that the tissue changes observed in the material removed from Plaintiff are the sort of changes – fibrosis, inflammation, and bridging – that can cause clinical symptoms such as pain. Defendants have offered no reason to call into doubt the reliability of that opinion.

This prong of the motion is denied.

VII. ECF No. 133 - Leigh Anne Levy, RN, MSN, CLCP, CEN

Levy is a Certified Life Care Planner ("CLCP") and nurse. Levy's Life Care Plan and Cost Analysis dated April 14, 2021 (ECF No. 133-2) addresses a variety of physical limitations alleged to be experienced by Plaintiff and the future care which may be needed due to such

alleged limitations. The plan is predominantly used for the purpose of determining an appropriate financial reserve to pay for future care. The Cost Analysis Summary provides there is a $3,437,011.72 Lifetime Cost. ECF No. 133-2 at PageID #: 13870.

A.

Defendants argue the Court should preclude Levy from offering life care plan recommendations which are not limited to or related to her TVT-O as such opinions are unreliable and misleading. Levy specifically admitted that not only is she unable to parse out which future care needs may be related to the TVT-O mesh, but that to do so is "outside [her] scope." Deposition of Leigh Anne Levy, R.N. (ECF No. 133-3) at PageID #: [124:21–125:9]. She makes no attempt to say whether the cost of Plaintiff's long-term care needs are related to the TVT-O or unrelated preexisting injuries and medical conditions.

B.

Next, Defendants argue the Court should preclude Levy from offering life care plan recommendations which are not relevant to the facts of this case. Also included in the projected care are medical treatments and costs which Plaintiff herself has admitted she will not pursue or are not necessary. As such, these treatments go beyond being speculative; they are completely irrelevant to Plaintiff's care and should be excluded. For example, Levy budgets $171,290 for future home modifications and another $11,000 for maintenance of modifications. However, Plaintiff testified that she has no difficulty ambulating around the home and that "[e]verything is very accessible." Excerpts from Deposition of Jane Olszeski (ECF No. 133-4) at PageID #: [8:13-19]. In fact, Plaintiff recently moved out of the home evaluated by Levy. ECF No. 133-4

at PageID #: [7:9-15]. Furthermore, Levy includes costs for future surgeries, such as future mesh removal procedures, ECF No. 133-2 at PageID #: [50], despite Plaintiff's testimony that she does not "even want to talk about that." ECF No. 133-4 at PageID #: [64:6-10].

C.

Finally, Defendants argue the Court should preclude Levy from offering opinions dependent on inadmissible expert opinions as such opinions lack reliable and admissible foundations. Levy based her recommendations solely on the opinions of Plaintiff's other experts (Drs. Rosenzweig and Hibner). *See* ECF No. 133-2 at PageID #: [1]. To the extent those other opinions are inadmissible, Levy's opinions should similarly be excluded.

The motion is denied. Counsel will have the opportunity at trial to examine Levy regarding costs that are not established to be caused by the TVT-O mesh. Any issues raised in this motion go not to the admissibility of the evidence, but to the weight of the evidence, and can be addressed *via* cross-examination and "presentation of contrary evidence" by opposing counsel. *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 596 (1993).

VIII. ECF No. 130 - David W. Boyd, Ph.D.

Dr. Boyd, an economist, is a damages expert that will provide an economic analysis estimating the present value of the Life Care Plan prepared by Leigh Anne Levy dated April 14, 2021. Defendants argue that without a proper foundation, Dr. Boyd's opinions are neither relevant nor helpful to the trier of fact under Fed. R. Evid. 702 and are thus inadmissible. Defendants, however, have not challenged Dr. Boyd's qualifications as an economist. Plaintiff contends his opinions are reliable and helpful to the jury.

The motion is denied for the reasons set forth above in Section VII with regard to Ms. Levy.

IT IS SO ORDERED.

April 8, 2022
Date

/s/ Benita Y. Pearson
Benita Y. Pearson
United States District Judge